

## **REMARKS**

The above amendments and these remarks are responsive to the Office action dated April 1, 2005. Claims 1-3 and 7-13 are pending in the application. Claims 1-3 and 7-13 are rejected. By way of the present amendment, claims 1 and 3 are amended and claims 7 and 9-13 are canceled. In view of the amendments above, and the remarks below, Applicants respectfully request reconsideration of the rejected claims.

### ***Amendments to the Claims***

Applicants suggest that the above amendments place the application in condition for allowance, or in the alternative place the rejected claims in better form for consideration on appeal. Applicants therefore respectfully request that the above amendments be entered.

### ***Rejections under 35 USC § 112***

Claims 7 and 9-13 are rejected under 35 U.S.C. § 112, first paragraph. The Examiner has indicated that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In particular, the Examiner suggests that the specification, while being enabling for inhibiting of production of MCP-1, does not reasonably provide enablement for an infection control or for treatment or prevention of decreases in infection resistance as encompassed by claims 7 and 9-13.

Without acknowledging the propriety of the rejections, Applicants have canceled claims 7 and 9-13. Applicants reserve the right to pursue the subject matter of the canceled claims in a continuing application. In view of the above amendment, Applicants suggest that the rejection of claims 7 and 9-13 is rendered moot.

***Rejections under 35 USC § 102***

Claims 1-3 and 8-13 are rejected under 35 U.S.C. § 102(b) as being anticipated by European Patent No. 0255 420, or in the alternative, claims 1-3 and 8-13 are rejected under 35 U.S.C. § 103(a) as being obvious over European Patent No. 0255 420 (hereafter Ito et al.). The Examiner has indicated that Ito et al. discloses a composition comprising glycyrrhizin and a method administering said composition, and that the inhibition of MCP-1 production would have been inherent in such an administration.

Without acknowledging the propriety of the rejections, Applicants have amended claim 1 to exclude the administration of the compound glycyrrhizin from the claimed subject matter. Applicants suggest that the cited references neither disclose nor suggest the inhibition of MCP-1 by the glycyrrhizin derivatives recited in claim 1.

More specifically, Ito et al. discloses the preparation and administration of glycyrrhizin, ammonium glycyrrhizinate, sodium glycyrrhizinate, and potassium glycyrrhizinate (see page 5, lines 1-25). Ito et al. fails to disclose the administration of the glycyrrhizin derivatives as recited in amended claim 1.

Further, Ito et al. fails to establish the *prima facie* obviousness of the method of claim 1. In order to establish *prima facie* obviousness, the cited reference must provide

some suggestion or motivation, in the prior art itself, to modify the reference so as to arrive at the claimed invention. Such motivation cannot be derived from Applicant's own specification. The cited reference must also provide a reasonable expectation of success. The prior art reference must teach or suggest each and every claim limitation.

Ito et al. provides no suggestion or motivation to administer any derivatives of glycyrrhizin to mammals. In particular, the cited reference fails to provide any specific suggestion or motivation to administer the specific derivatives recited in claim 1, as well as failing to suggest the desirability of making such a modification.

Ito et al. fails to provide a reasonable expectation of success for the claimed invention. One cannot base a determination of obviousness on what a skilled artisan might try, or even find obvious to try. Rather, obviousness is determined by what the prior art would lead the skilled artisan to do. The cited reference fails to provide a reasonable expectation that the recited glycyrrhizin derivatives would also be effective in inhibiting MCP-1 production, particularly an art where biological activity is so sensitive to even small differences in chemical structure.

Additionally, as discussed above, the Ito et al. reference fails to recite each and every element of the rejected claims. In particular, the cited reference fails to disclose the specific recited glycyrrhizin derivatives of claim 1.

For at least the above reasons, Applicants suggest claim 1 is not anticipated by Ito et al., and further that the Examiner has failed to establish the *prima facie* obviousness of claim 1. As claims 2, 3, and 8 depend directly or indirectly from claim 1, Applicants suggest that they are similarly not anticipated or rendered *prima facie* obvious by the

cited reference. Applicants therefore request the withdrawal of the rejection of claims 1-3 and 8 under 35 U.S.C. §§ 102 and/or 103.

Claim 7 has been rejected under 35 U.S.C. § 102(b) as being anticipated by European Patent No. 0255 420. In particular, the Examiner suggests that Ito et al. discloses the claimed composition comprising glycyrrhizin and carriers. As indicated above, in view of the above amendments Applicants suggest that the rejection of claim 7 has been rendered moot.

Claims 1-3 and 8-13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Takei et al. (Abstract T-14, ASM 101st General Meeting, 5/22/2001). The Examiner indicates that Takei discloses that glycyrrhizin is effective in inhibiting MCP-1 and discloses that MCP-1 has been reported to stimulate HIV replication. Therefore, a person having ordinary skill in the art at the time the instant invention was made would have been motivated to use glycyrrhizin for the treatment of mammals in need of inhibiting of MCP-1 and for mammals having HIV infection.

As indicated above, Applicants have amended claim 1 to exclude the administration of the compound glycyrrhizin from the claimed subject matter. Applicants suggest that the cited references neither disclose nor suggest the inhibition of MCP-1 by the recited glycyrrhizin derivatives.

The Takei et al. reference describes the inhibition of MCP-1 by glycyrrhizin in peripheral blood mononuclear cells derived from AIDS patients. However, the Takei et

al. reference fails to disclose the administration of the glycyrrhizin derivatives of amended claim 1.

Applicants suggest that Takei et al. provides no suggestion or motivation to administer any of the recited derivatives of glycyrrhizin to mammals, and fails to suggest the desirability of modifying the reference to arrive at the claimed invention. Takei et al. similarly fails to provide a reasonable expectation of success for the claimed invention, and fails to recite each and every element of the rejected claims.

For at least the above reasons, Applicants suggest that the Examiner has failed to establish the *prima facie* obviousness of claim 1. As claims 2, 3, and 8 depend directly or indirectly from claim 1, Applicants suggest that they are similarly not rendered *prima facie* obvious by Takei et al. Applicants therefore request the withdrawal of the rejection of claims 1-3 and 8 under 35 U.S.C. § 103.

It is believed that the subject patent application has been placed in condition for allowance, and such action is respectfully requested. If the Examiner has any questions or concerns, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned agent of record.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 11-1540.


**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on September 1, 2005.

  
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